

# TRANSMITTAL FORM

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<b>TRANSMITTAL FORM</b> be used for all correspondence after initial filing)		Application Number	10/086,294
		Filing Date	February 28, 2002
		First Named Inventor	Nielsen, Loretta
		Art Unit	1635
		Examiner Name	Lacourciere, K.
Total Number of Pages in This Submission		Attorney Docket Number	016930-003712US

## ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Preliminary Amendment <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s)	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Return Postcard PTO/SB/08A and /08B Form 0 Reference Copies
Remarks		The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	Townsend and Townsend and Crew LLP		
	Nathan S. Cassell	Reg. No. 42,396	
Signature	<i>Nathan Cassell</i>		
Date	3-1-04		

## CERTIFICATE OF TRANSMISSION/MAILING

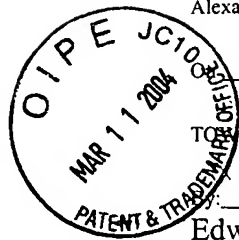
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name	Edward Masinas		
Signature	<i>Edward Masinas</i>	Date	3-8-04

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

PATENT  
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3-8-04

TOWNSEND and TOWNSEND and CREW LLP

*Edward Masinas*  
Edward Masinas

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Nielsen et al.

Application No.: 10/086,294

Filed: February 28, 2002

For: COMBINED TUMOR  
SUPPRESSOR GENE THERAPY AND  
CHEMOTHERAPY IN THE  
TREATMENT OF NEOPLASMS

Examiner: Lacourciere, K.

Art Unit: 1635

INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR §1.97 and  
§1.98

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. In accordance with 37 CFR §1.98(d), copies of the references can be found in Application No. 09/024,932, filed February 17, 1998 (Attorney Docket No. 016930-003710US). It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

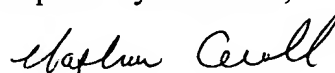
As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no

representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement.

However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Nathan S. Cassell  
Reg. No. 42,396

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60142442 v1



<b>Substitute for form 1449A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>	
			Application Number	10/086,294
			Filing Date	February 28, 2002
			First Named Inventor	Nielsen, Loretta
			Art Unit	1635
Sheet	1	of	Examiner Name	Lacourciere, K.
			Attorney Docket Number	016930-003712US

U.S. PATENT DOCUMENTS+					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code <sup>2</sup> (if known)			
	AA	US-6,054,467	04-25-2000	Gjerset	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
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Substitute for form 1449B/PTO			<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>			<i>Application Number</i>	10/086,294
			<i>Filing Date</i>	February 28, 2002
			<i>First Named Inventor</i>	Nielsen, Loretta
			<i>Art Unit</i>	1635
			<i>Examiner Name</i>	Lacourciere, K.
			<i>Attorney Docket Number</i>	016930-003712US
Sheet	2	of		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AB	Blagosklonny, <i>et al.</i> , "In Vitro Evaluation of A p53-Expressing Adenovirus As An Anti-Cancer Drug," <i>Int. J. Cancer</i> 67:386-392 (1996)	
	AC	Brinckerhoff, <i>et al.</i> , <i>Human Gene Therapy</i> 6:1065-1124 (August 1995)	
	AD	Chang, <i>et al.</i> , "Restoration of the G <sub>1</sub> Checkpoint and the Apoptotic Pathway Mediated by Wild-type p53 Sensitizes Squamous Cell Carcinoma of the Head and Neck to Radiotherapy," <i>Arch Otolaryngol Head Neck Surg.</i> , 123:507-512 (1997)	
	AE	Delia, <i>et al.</i> , <i>Nature Medicine</i> 2(7):724-725 (July 1996)	
	AF	Fujiwara, <i>et al.</i> , "Induction of chemosensitivity in human lung cancer cells <i>in Vivo</i> by adenovirus-mediated transfer of the wild-type p53 gene," <i>Cancer Research</i> 54:2287-2291 (1994)	
	AG	Frank, <i>et al.</i> , "Combination E2F-1 and p53 Gene Transfer Does Not Enhance Growth Inhibition in Human Squamous Cell Carcinoma of the Head and Neck," <i>Clin. Cancer Research</i> 4:2265-2272 (1998)	
	AH	Gallardo, <i>et al.</i> , "Adenovirus-based Transfer of Wild-Type p53 Gene Increases Ovarian Tumor Radiosensitivity," <i>Cancer Research</i> 56:4891-4893 (1996)	
	AI	Gjerset, <i>et al.</i> , "Use of Wild-Type p53 to Achieve Complete Treatment Sensitization of Tumor Cells Expressing Endogenous Mutant p53," <i>Molecular Carcinogenesis</i> 14:275-285 (1995)	
	AJ	Gurnani, <i>et al.</i> , "Adenovirus-mediated p53 gene therapy has greater efficacy when combined with chemotherapy against human head and neck, ovarian, prostate, and breast cancer," <i>Cancer Chemother Pharmacol.</i> 44:143-151 (1999)	
	AK	Hehir, <i>et al.</i> , <i>Journal of Virology</i> 70(12):8459-8467 (December 1996)	
	AL	Kalechman, <i>et al.</i> , <i>Journal of Immunology</i> 156(3):1101-1109 (1996)	
	AM	Nguyen, <i>et al.</i> , "Gene therapy for lung cancer: enhancement of tumor suppression by a combination of sequential systemic cisplatin and adenovirus-mediated p53 gene transfer," <i>J. Thorac. Cardiovasc. Surg.</i> 112:1372-1377 (1996)	
	AN	Nielsen, <i>et al.</i> , "Adenovirus-mediated p53 Gene Therapy and Paclitaxel Have Synergistic Efficacy in Models of Human Head and Neck, Ovarian, Prostate, and Breast Cancer," <i>Clin. Cancer Research</i> 4:835-846 (1998)	

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<sup>1</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3

of

**Complete if Known**

Application Number	10/086,294
Filing Date	February 28, 2002
First Named Inventor	Nielsen, Loretta
Art Unit	1635
Examiner Name	Lacourciere, K.
Attorney Docket Number	016930-003712US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AO	Ogawa, <i>et al.</i> , "Novel combination therapy for human colon cancer with adenovirus-mediated wild-type p53 gene transfer and DNA-damaging chemotherapeutic agent," <i>Int. J. Cancer</i> 73:367-370 (1997)	
	AP	Parsels, <i>et al.</i> , "Prevention of Fluorodeoxyuridine-Induced Cytotoxicity and DNA Damage in HT29 Colon Carcinoma Cells by Conditional Expression of Wild-Type p53 Phenotype," <i>Molecular Pharmacology</i> 52:600-605 (1997)	
	AQ	Pirollo, <i>et al.</i> , "p53 mediated sensitization of squamous cell carcinoma of the head and neck to radiotherapy," <i>Oncogene</i> , 14:1735-1746 (1997)	
	AR	Sandig, <i>et al.</i> , "Adenovirally transferred <i>p16<sup>INK4/CDKN2</sup></i> and <i>p53</i> genes cooperate to induce apoptotic tumor cell death," <i>Nature Med.</i> , 3:313-319 (1997)	
	AS	Spitz, <i>et al.</i> , "In Vivo Adenovirus-Mediated p53 Tumor Suppressor Gene Therapy for Colorectal Cancer," <i>Anticancer Research</i> , 16:3415-3422 (1996)	
	AT	Spitz, <i>et al.</i> , "Adenoviral-mediated Wild-Type p53 Gene Expression Sensitizes Colorectal Cancer Cells to Ionizing Radiation," <i>Clin. Cancer Research</i> 2:1665-1671 (1996)	
	AU	Son, <i>et al.</i> "Exposure of human ovarian carcinoma to cisplatin transiently sensitizes the tumor cells for liposome-mediated gene transfer," <i>Proc. Natl. Acad. Sci. USA</i> , 91:12669-12672 (1994)	
	AV	Tishler, <i>et al.</i> , <i>British Journal of Cancer</i> 74(27):S82-S85 (1996)	

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Examiner Signature		Date Considered	
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